B1 Sub C1

1. A unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about 3 hours.

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15. A unit dosage form according to claim 1, wherein said taxane is docetaxel.

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30. A unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 40 mg/m^2 to about 800 mg/m^2 with a cycle time of no greater than about three weeks between administrations of said total dose.

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43. A unit dosage form according to claim 30, wherein said taxane is docetaxel.

58. A unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said sealed vial comprises in the range of about 4 mg to about 822 mg of said taxane.

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59. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 4 mg to about 13 mg of said taxane.

60. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 13 mg to about 30 mg of said taxane.

61. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 20 mg to about 69 mg of said taxane.

62. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 45 mg to about 69 mg of said taxane.

63. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 69 mg to about 90 mg of said taxane.

64. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 69 mg to about 103 mg of said taxane.

B5 cancel

65. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 103 mg to about 120 mg of said taxane.

66. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 103 mg to about 148 mg of said taxane.

67. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 120 mg to about 367 mg of said taxane.

68. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 148.1 mg to about 367 mg of said taxane.

69. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 367 mg to about 548 mg of said taxane.

70. A unit dosage form according to claim 58, wherein said sealed vial comprises in the range of about 367 mg to about 822 mg of said taxane.

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77. A unit dosage form according to claim 58, wherein said taxane is docetaxel.

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98. A unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

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100. A unit dosage form according to claim 98, wherein said taxane is docetaxel.

B9 104. A unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

B10 106. A unit dosage form according to claim 104, wherein said taxane is docetaxel.

B11 110. A unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of primary tumors.

B12 112. A unit dosage form according to claim 110, wherein said taxane is docetaxel.

B13 116. A unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of metastatic tumors.

B14 118. A unit dosage form according to claim 116, wherein said taxane is docetaxel.

B15 122. A unit dosage form comprising a sealed vial containing a quantity of a formulation of taxane sufficient to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said formulation does not leach plasticizer.

B16 124. A unit dosage form according to claim 122, wherein said taxane is docetaxel.

B17 128. A taxane containing formulation contained within a sealed vial suitable for the delivery of a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, with an administration period of no greater than about 3 hours.

B18 130. A formulation according to claim 129, wherein said taxane is docetaxel.

B19 133. A taxane containing formulation contained within a sealed vial suitable for the delivery of a total dose of taxane in the range of about 80 mg/m^2 to about 700 mg/m^2, with a treatment cycle of no greater than about 3 weeks.

B19 Cancel.

134. A formulation according to claim 133, wherein said taxane is docetaxel.

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137. A unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to allow systemic administration to a subject, employing a standard intravenous infusion set, of a total dose in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane.

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140. A unit dosage form according to claim 137, wherein said taxane is docetaxel.

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145. A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation contained within a sealed vial with a treatment cycle no greater than about 3 weeks.

146. A method according to claim 145, wherein said taxane is docetaxel.

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149. A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation contained within a sealed vial with an administration period no greater than about 3 hours.

150. A method according to claim 149, wherein said taxane is docetaxel.

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156. A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

157. A method according to claim 156, wherein said taxane is docetaxel.

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160. A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of

B25 cancel.

about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

161. A method according to claim 160, wherein said taxane is docetaxel.

164. A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

165. A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

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166. A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

167. A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

168. A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane does not leach plasticizer from administration devices used to administer said unit dosage formulation.

169. A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel does not leach plasticizer from administration devices used to administer said unit dosage formulation.

170. A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

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171. A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

172. A unit dosage form of paclitaxel comprising an article of manufacture, wherein said article comprises a sealed vial containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over an administration period no greater than about 3 hours.

173. A unit dosage form of paclitaxel comprising an article of manufacture containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over an administration period no greater than about 3 hours.

174. An article of manufacture comprising paclitaxel suitable for administration to a human over an administration period no greater than about 3 hours, said article comprising a

sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over said administration period.

175. An article of manufacture comprising paclitaxel suitable for administration to a human over an administration period no greater than about 3 hours, said article comprising a sealed vial containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over said administration period.

176. An article of manufacture comprising paclitaxel suitable for administration to a human over an administration period no greater than about 3 hours, said article comprising a sealed vial containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over said administration period.

177. A lyophilized taxane-containing formulation characterized by the ability to be reconstituted at concentrations greater than 1.3 mg/ml, and remaining stable for at least 3 days, wherein said taxane is docetaxel.

REMARKS

In accordance with the present invention, there are provided unit dosage forms of taxanes, formulations thereof, and methods for use thereof. Invention unit dosage forms allow systemic administration to a human subject in need thereof at dose levels and over administration periods and/or treatment cycles not previously possible. Due to the larger amounts of taxanes provided by invention unit dosage forms, the present invention offers both markedly improved therapeutic benefits and dramatically reduced administration periods, thereby alleviating discomfort experienced by a subject in need thereof.